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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,051	02/20/2002	Anthony F. Barbet	UF-299XC1	1773
23557 7590 04/28/2004 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION 2421 N.W. 41ST STREET SUITE A-1 GAINESVILLE, FL 326066669			EXAMINER BASKAR, PADMAVATHI	
			ART UNIT 1645	PAPER NUMBER

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/081,051

Applicant(s)

BARBET ET AL.

Examiner

Padmavathi v Baskar

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

18-20

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/21/03, 6/20/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Applicant's response to restriction requirement and preliminary amendment filed on 2/5/04 is acknowledged.

Election

2. Acknowledgment is made of Applicant's election of Group I, claims 1-7 and 16 without traverse drawn to polynucleotide with respect to SEQ.ID.NO: 52.

Status of Claims

3. Claims 1 and 7 have been amended.

Claims 8-17 have been canceled.

New Claims 18-20 have been added.

Claims 1-7 and 18-20 are pending in the application.

Claims 18-20 are drawn to an isolated polypeptide and a method of making a polypeptide. New claims are drawn to a non-elected invention, i.e., polypeptide, said election being made on 2/5/04 and are therefore withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 1-7 are under examination. A First Action on the Merits on these claims is issued.

Priority

4. Applicant's claim for domestic priority to provisional application 60/269,944 (2/20/010) under 35 U.S.C. 119(e) is acknowledged.

Information Disclosure Statement

5. Acknowledgment is made of ~~the~~ Information Disclosure Statements filed 01/21/03 and 6/20/03. A signed copy of each is attached to this Office action.

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Claim Informalities

6. Claim 2 implies that the isolated polynucleotide sequence comprises more than one regulatory element (i.e., elements) and more than one expression system (i.e., systems)? Is this polynucleotide sequence in part expressed in more than one expression system having its own regulatory element? Or is the isolated polynucleotide sequence as set forth in SEQ.ID.NO: 52 as a whole expressed in different expression systems?

Claim 7 recites "a host cell comprising a polynucleotide sequence". Does applicant intend to mean an isolated host cell transformed by a vector comprising the polynucleotide sequence according to claim 1?

Rejection(s) under 35 U.S.C. § 101

7. 35 U.S.C. 101 reads as Follows

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

8. Claim 7 is rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. To overcome this rejection the Examiner suggests the amendment of the claims to include "isolated" so that it is "free of" relative to the natural source. (see Farbenfabriken of Elberfeld Co. v. Kuehmsted, 171 Fed. 887, 890 (N.D. Ill. 1909) (text of claim at 889); Parke-Davis & Co. v. H.D. Mulford Co., 189 Fed. 95, 103, 106, 965 (S.D.N.Y. 1911) (claim 1); and In re Bergstrom, 427 F.2d 1394, 1398, 1401-1402 (CCPA 1970).

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter, which the Applicant regards as his/her invention

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10. Claims 1-7 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague for the recitation of "an isolated polynucleotide sequence comprising SEQ.ID.NO: 52". The expression SEQ.ID.NO is generally used to identify a sequence. For the purpose of distinctly claiming the subject matter, it is proper to recite the claim as "an isolated polynucleotide comprising the nucleotide sequence SEQ.ID.NO: 52" Or "an isolated polynucleotide sequence as set forth in SEQ.ID.NO: 52".

Claim 2 is vague for recitation of "capable of causing the expression" It has been held that an element is capable of Forming a color is not a positive limitation but only requires the ability to perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69USPQ 138.

Claim 2 is rejected as vague for the recitation of " optionally", It is not clear how does one determine whether or not a polynucleotide sequence encoding a heterologous polypeptide is optional?

Remarks

9. Claims 1-7 are rejected.

10. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the

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status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

4/13/04


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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